Navajo Nation Human Research Review Board Meeting Agenda

Meeting Date: 2022-04-19 Meeting Time: 9:00 AM

Location: Teleconference

Teleconference Call-in Number: 978-990-5350, Access Code:

5891214

MEMBERS:	OLD BUSINESS:
Mrs. Beverly Becenti-Pigman - Community	I. Meeting Call to Order:
Dr. David Begay, Ph.D Scientific Education	II. Roll Call:
Mr. Delvin Yazzie, MPH - Epidemiology Dr. Kalvin White, Ph.D Scientific Education	- Invocation:
Dr. Nanibaa' Garrison, Ph.D Genetics, Bio-Ethics Dr. Rebecca Izzo-Manymules, Ph.D Chairperson - Education Dr. Sonya Shin, MD - Medicine Ms. Ursula Knoki-Wilson, MSN, MPH - Nursing	
	III. Review and Approval of Agenda:
	IV. Review and Approval November 15, 2021 Meeting Minutes:
	NEW BURNESS
	NEW BUSINESS: V. Review and Approval of Quarterly Reports:
	VI. New Presentations:
	VII. Returning Presentations:
	VIII. Serious Adverse Events:
	IX. Noon Hour Discussion: DOJ Recommendation on Creighton University Study
	X. Acceptance and Approval of Manuscripts: 1) 17.277, Examing awareness, knowledgement, Health Beliefs - Charron-Prochownik, PhD. 2) 18.316, Developing STEAM curriculum units to Engaging 4th - 8th Grade - Deidra Hunter PhD. 3) 21.419. Measuring the Effects of the COVID-

19 Pandemic on Din'e and White Mountain Apache School. 4) 19.350, 21424, Effectiveness of COVID-19 mRNA vaccines among AI/AN persons January-November 2021 - Laura Hammitt. 5) 19.350 Respiratory syncytial virus associated hospitalizations in AI/AN Children, pregnant women 2019-2020 - Laura Hammitt. 6) 17.284. Practicing Tribal Sovereignty through Tribal Health Policy - Regina Eddie. 7) 11.342 The relationship between AII-cause Dementia and Acute Diabetes Complications among AI/AN people - Joan O'Connell, PhD

XI. Announcements / Adjournments

QUARTERLY REPORTS

1. NNR-11.323 PI: Johnnye Lewis

Navajo Birth Cohort Study (NBCS)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 23, 2021 - February 22, 2022 period

2. NNR-11.348 PI: Simental Francisco

Navajo Behavioral Risk Factor Surveillance Survey

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1, 2022 - March 31, 2022 period

3. NNR-15.231 PI: Sara Selig

Engaging Patients and Stakeholders to Improve Cancer Outcomes in Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering December 15, 2021 - March 15, 2022 period

4. NNR-16.245 PI: Joel Gittelsohn

Engaging Tribal Policy Makers to Sustain Improvements to the Food and Physical Activity in American Indian Communities (OPREVENT2)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1, 2022 - March 31, 2022 period

5. NNR-16.247 PI: Bruce Bender

Creating an asthma collaboration to reduce childhood asthma disparities on the Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 2022 - March 2022 period

6. NNR-17.287 PI: Hannah Sehn

Understanding the Structural Barriers and Opportunities to Improve Cancer Treatment on Navajo Nation Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering December 15, 2021 - March 15, 2022 period

7. NNR-19.360 PI: Debra MacKenzie

Navajo Birth Cohort Study/environmental Influences on Child Health Outcomes Plus (NBCS/ECHO+)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering December 18, 2021 - March 17, 2022 period

8. NNR-19.367 PI: Craig Chaya

Patterns of Blindness in the Navajo Nation: A Retrospective Study

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 2022 - March 2022 period

9. NNR-20.384 PI: Dornell Pete

Assessing the Gut MicroBiota and Individual Diet in the Navajo ('Abid Study)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering December 15, 2021 - March 17, 2022 period

10. NNR-21.425 PI: Lynn Gerald

Healthy Hooghans Pilot Project

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 9, 2022 - March 25,2022 period

11. NNR-10.287 PI: Joel Gittelsohn

Multilevel Obesity Prevention Trial for American Indian Community (OPREVENT)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1, 2022 - March 31, 2022 period

NEW PRESENTATION(S)

1. NNR-22.440 PI: Antoinette Vree Vreeke

The Effects of COVID-19 Pandemic on the Mental Health and Stress Navajo Nation Adultsâ as a Thesis to fulfill degree requirements at University of Washington

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 04/04/2022

2. NNR-22.441 PI: Eleanor Jones

Holistic Pedagogy: The Need for a Culturally Responsive Curriculum for Schools on the Navajo Nation.

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 04/04/2022

RETURNING PRESENTATION(S)

1. NNR-11.349 PI: Mark Bauer

Navajo Gardening, Nutriiton, and Community Wellness

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering April 17, 2022 - Aparil 17, 2023 period

2. NNR-16.244 PI: Mark Bauer

Identifying and Reinforcing Positive Behaviors among Dine' College Students

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering April 19, 2022 - April 19, 2023 period

3. NNR-21.412 PI: Joel Gittelsohn

Formative Research to Improve WIC Participation in Three Diverse Native American Communities Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approva of 3 Abstracts titled: 1-A participatory Sstme sapproach to understang IC participating in rural Native American communites; 2- Identifying strategies to improve enrollment and participation in three rural Native American Programs; 3-Identifying Strategies to Improve American Indian Women's Participation in the Federal Nutrition Program for Women, Infants, and Children at American Society for Nutrition Annual Meeting on June 14-16, 2022.

4. NNR-18.302 PI: Mark Bauer

Navajo NARCH Partnership: Evaluation of the Student Enhancement Program

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments 1-High School outreach program: * Digital Storytelling Parental Consent for participation in DST evaluation, -Student Assent for DST, Evaluation Form for DST, * Research Internship for High School Parental Consent for participation in the Internship, -Student Assent for the Internship evaluation, Evaluation Form for the Internship, * Indigenous Student Enhancement Program (ISEP) Peer Mentor Evaluation: Parental Consent for participation in the ISEP Peer Mentor Evaluation, Pre-Survey for the ISEP Peer Mentor Experienc,

Post Survey for ISEP Peer Mentor Experience. Seven existing evaluation forms and six associated consent forms.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering April 17, 2022 - April 17, 2023 period

5. NNR-20.385 PI: Geraldine Garrity

A Study on the Bureau of Indian Education (BIE) Navajo Language Immersion Programs

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of quarterly Report covering August 2021 - March 31, 2022 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 1, 2021 - July 31, 2022 period

6. NNR-16.263 PI: Robin Harris

Helicobacter Pylori Infection and Stomach Cancer

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of 4 Questionnaires: 1-Household Census, 2-Household Questionnaires, 3-Individuals Questionnaires and Individual Beliefs and Perceptins, 4-Food Frequency Questionnaies.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Recruitment Flyer for semi-structured interviews.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Consent Form (on-line, telephone)

7. NNR-21.426 PI: Sonya Shin

Global learning to Advance Health Equity: A Learning network

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments: 1-invite sites to apply funds to carry out a 9-months global health equity project of their choice; 2-to alllow the Four Corners CPHE team to carry out gardening, youth programming; 3-Northern Agency Council Resolution obtained to interview individuals residing within Four Corners region.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 16, 2021 - February 16, 2022 period

8. NNR-15.223 PI: Jennifer Richards

Formative Research to Inform the Development of an Intergenerational Strengths-Based Program for American Indian Girls as they Transition to Adulthood.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to Caregivers survey to add new questions about their awarness of doulas.

Reason on Agenda: Addition of Co-Investigator

Description: Request Acceptance of Amendment to add 2 Co-PI: Rachel Chambers and Lauren Tingey.

9. NNR-16.264 PI: Allison Barlow

Preventing Early Childhood Obesity, Part I: Family Spirit Nurture, 3-9 Months, Part II: 18 Months Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Conference Presentation 2 Presentations at New Mexico Public Health Association on May 19-20, 2022 by virtually. Titles: 1-Family Spirit Nurture; Examing Long-Term Impacts; 2-Din'e Hydration Project: Exploring Water Security and Child Health.

10. NNR-21.419 PI: Joshuaa Allison-Burbank

Project Safe Schools: Re-opening schools serving Native children and adolescents SAFELY

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to request permission to contact study participants about

future Studies. an opt-in bullent added in Consent/permission/assent forms.

11. NNR-21.397T PI: Manley Begay, Jr.

Understanding Resilience and Mental Wellbeing: Southwest Indigenous Nations and the Impact of COVID-19 Reason on Agenda: Quarterly Review

Description: Request review and Acceptance of Quarterly Report covering December 25, 2021 - March 24, 2022 period

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract Titled: Two Eyed Seeing Qualitative Analysis: A Case Study for

American Public Health Association 150th Annual Meeting and Expo on November 6-9, 2022.

12. NNR-11.342 PI: Joan O'Connell

Comparative Effectiveness of Healthcare Delivery Systems for American Indian and Alaska Native using

Enhanced Data Infrastructure

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering May 15, 2022 - May 15, 2023

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report ending December 2021 period

13. NNR-19.347 PI: Davis Henderson

Navajo Children with and without Speech Sound Disorders

Reason on Agenda: (Other)

Description: Request Acceptance and Approval to Add Student Tracilynn Carl to assist Dr. Henderson, PhD, attacted CITI

Certificate

14. NNR-19.332 PI: Gyan Nyaupane

Understanding the changing relationships of Indigenous peoples with their natural environments: A cross-cultural Study

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering February 19, 2022 - February 19, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 19, 2020 - February 19, 2021 period.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) November 2020 - January 2021; 2) February 2021 - April 2021; 3) May 2021 - July 2021, 4) August 2021 - October 2021 periods

SERIOUS ADVERSE EVENT

1. NNR-02.110 PI: Vallabh Shah

Diabetes Prevention Program Outcomes Study (DPPOS)

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: COVID-19

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: COVID-19

2. NNR-20.381 PI: Laura Hammitt

A Phase 1/2/3 Placebo-Controlled, Randomized, Observer-Blind, Dose-Find Study to Evaluate the Safety, Tolerability, Immunigenicity, and Efficacy of SARs-COV 2 RNA Vaccine Candidates Against COVID-19 in Healthy Adults (Short Title: Pfizer COVID-19 Vaccine Study)

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Myocardial infarction

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: TIA (transient ischemic attack)

Reason on Agenda: Primary - Off Site SAE

Description:

diagnosis: Pancreatitis